Philip Morris USA/Covance
Agenda
Wednesday, April 24, 2002
Boardroom

***Candace Adams, PhD, Smoking Behavior Coordinator, Philip Morris USA**
Hans Carter, PhD, Professor, Department Head, Department of Biostatistics, Virginia Commonwealth University
***Shixia Feng, PhD, Bioanalytical/Organic Chemist, Philip Morris USA**
Chris Gennings, PhD, Associate Professor, Department of Biostatistics, Virginia Commonwealth University
Robert Johnson, PhD, Associate Professor, Department of Biostatistics, Virginia Commonwealth University
***Robin Kinser, PhD, Analytical Coordinator, Philip Morris USA (via audio conference)**
***Bettie Nelson, Dr., PH Biostatistical Coordinator, Philip Morris USA**
***Jan Oey, PhD, Project Coordinator, Philip Morris USA**
Hans-Juergen Roethig, MD, PhD, Medical Director, Philip Morris USA
Roger Walk, PhD, Director, Worldwide Scientific Affairs, Philip Morris USA
Barbara Zedler, MD, Consultant, Clinical Research

*** Philip Morris USA core team members.**

Rachid Chaouki, MS, Statistician, Data Manager, Covance CRU - Madison
Jenifer Dean, RN, CCRC, CCRP, Associate Director, Clinical Operations, Covance CRU - Madison
Russell Dixon, MD, Medical Director, Covance CRU - Madison
Jayme Garrett, CCRP, Senior Project Coordinator, Clinical Operations, Covance CRU - Madison
John Hunter, MS, Manager, Biostatistics, Covance CRU - Madison
Traci Janisch, CCRP, Supervisor, Medical Writing/Editing, Covance CRU - Madison
Megan Kamps, Supervisor, Clinical Operations, Covance CRU - Madison
Brigitte Kochan, CCRC, Manager, Client Services, Covance CRU - Madison
Eric Larson, SAS Programmer, Covance CRU - Madison
Mary Larson, RN, CCRC, CCRP, Senior Project Manager, Covance CRU - Madison
Keith Phillips, Director, Analytical Services, Covance Laboratories - Europe
Jill Schultz, Drug Development Consultant, Covance Consulting Services, Covance Laboratories - Madison
Mary Westrick, PhD, Global Vice President, Clinical Pharmacology, Covance CRU - Madison

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7:40 a.m.	Pick up at Hotel	B. Kochan, J. Schultz
8:00 a.m.	Arrival	All
8:15 a.m.	Review of Clinical Performance	J. Dean, M. Larson, M. Westrick
9:00 a.m.	Protocol Design for Total Exposure Study (TES)	All

1. Which biomarkers and markers of exposure will be included in protocol?
   - Which chosen marker is most variable?
   - Type of sample processing required
2. Inclusion/exclusion criteria
3. Smoking attributes - C. Adams
   - Questionnaire
   - Smoking topography

12:00 p.m.	Lunch (Cafeteria)	R. Chaouki, J. Dean, R. Dixon, J. Garrett, J. Hunter, T. Janisch, M. Kamps, B. Kochan, E. Larson, M. Larson, J. Schultz, M. Westrick
1:00 p.m.	Discussion of Protocol Design for TES Continued	All

4. Sampling strategy - B. Nelson
   - Geographical spread
   - Strata
   - Number of visits/volunteer (i.e., screening + one visit)
   - Sample size estimate

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2:00 p.m. Site Identification/Selection/Management — All

1. Review site feasibility/selection process and timeline
   - General mail/fax survey of interest/initiate CDA
   - Receipt of signed CDA
   - Positive response/review of responses
   - Send synopsis/detailed questionnaire/draft contract/budget template
   - Receipt of questionnaire/review of detailed responses/budget
   - Budget/contract negotiations/site indemnification
   - Central IRB - Covance
   - Standard Informed Consent Form

2. Site audits
   - Qualify site, SOP, training records, etc.
   - Assess sample processing capabilities/experience
   - Necessary equipment

3. Monitor visit schedule
   - Qualifying visit
   - Initiation (2-day visit, observe sample processing)
   - Interim (5-day visit, i.e., review 20 subject folders/day)
   - Close-out

4. Investigator meeting date/agenda
   - Venue
   - Responsibility

5. Arrangements

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4:00 p.m.	Departure for Hotel	B. Kochan, J. Schultz
6:00 p.m.	Pick up at Hotel for Dinner	B. Kochan, J. Schultz
6:30 p.m.	Dinner - Johnny Delmonicos	R. Chaouki, R. Dixon, B. Kochan, M. Larson, K. Phillips, J. Schultz, M. Westrick